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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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MICHAEL BEST & FRIEDRICH, LLP
ONE SOUTH PINCKNEY STREET
P O BOX 1806
MADISON, WI 53701

EXAMINER

ZALUKAEVA, TATYANA

ART UNIT	PAPER NUMBER
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1713

DATE MAILED: 08/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/917,971

Applicant(s)

MENTAK, KHALID

Examiner

Tatyana Zalukaeva

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 30 July 2001.

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 33-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 33-37 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some * c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other:

DETAILED ACTION

Claim Objections

1. Claim 34 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The difference in volume % between the hydrated and non-hydrated lens as per claim 34 is basically the same as "where the hydrated intraocular lens has an equilibrium water content less than about 10 weight %" as per claim 33 (taking into account the density of water equals to 1g/cm^3).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 33, 34 and 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Stoy (U.S. 4,731,079).

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Stoy discloses a method of making an intraocular lens (IOL), the embodiment presented in Example 2 clearly reads on the limitations of the instant claims 33, 34 and 37.

Thus, 85 grams of benzyl Acrylate, (first monomer of the instant claim 33) 15 grams of styrene (second monomer of the instant claim 33) and 0.35 grams of tetraethyleneglycol-bis-methacrylate (third monomer of the instant claim 33) were polymerized under nitrogen by means of 0.075 grams of benzoylperoxide.

Glass transition temperature T_g was 25.5° C. and the refractive index was 1.570.

The copolymer was lathed into the shape of a biconvex lens.

The lens was then inserted in a tube made from a roll of stainless steel, 0.5 mm in thickness. The roll and the lens were immersed in nearly boiling water for several seconds. Then the roll containing the deformed lens was immersed in a jar of saline. (this is a hydrating step) The deformed (or foldable) lens was readily insertable through a facoemulsification incision by means of forceps or another suitable instrument. (see Example II in columns 14 and 15). This meets the limitations of the instant claims 33 and 37.

According to Stoy, when the finished lens is placed in an isotonic saline solution for 24 hours at ambient temperature, from the lens' weight increase it was found that its equilibrium water content was about 10% by weight. (column 16, lines 10-15).

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Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claim 35 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Stoy.

The property of central thickness is not elucidated by Stoy. However, there are two aspects Examiner would like to address here. The first one is that since the polymers of Stoy are essentially the same as instantly claimed, and they are made via essentially the same method as instantly claimed, therefore the properties even not taught, will be inherently the same as a per *In re Fitzgerald* (205 USPQ 594). (CAFC) The onus to show that this, in fact, is not the case is shifted to applicants

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The second consideration is that Stoy teaches that at 31.5 Diopters the central thickness is 0.73 mm. If the proportion works in this case (taking into account the identity of the claimed and disclosed products) than the thickness at 20 Diopters should be close the claimed range $(20 \times 0.73 / 31.5) = 0.46$.

7. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoy. Stoy does not specify the sequence of hydrating steps.

However, Stoy clearly suggest plasticizing with water or saline solution, and suggests different modes of such plastification. Considering the absence of criticality of the particular mode of hydration, and the generic teaching of Stoy with regard to hydration, a person skilled in the art would have found it obvious to utilize any mode including one of the instant claims with the reasonable expectation of success. *In re Burhans* 69 USPQ 330 (CCPA 1946):

Selection of any order of performing process steps is prima facie obvious in the absence of new and unexpected results

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tatyana Zalukaeva whose telephone number is (703) 308-8819. The examiner can normally be reached on 9:00 - 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (703) 308-2450. The fax phone numbers for

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the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0651.



August 6, 2002

Tatyana Zalukaeva
Examiner
Art Unit 1713